DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 05 November 2007 has been entered in full. Claims 1-8, 10 are amended.

Election/Restrictions

Applicant's election of Group I, claims 1-10, 17-18, drawn to an isolated polypeptide comprising a functional SLC26A6 polypeptide of SEQ ID NO: 2 or 4 in the reply filed on 05 November 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 11-16 and 19-87 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 05 November 2007.

Claims 1-10 and 17-18 are under consideration in the instant application as they read upon the amino acid sequence of SEQ ID NO: 2 or 4 (and the polypeptides encoded by the nucleic acid sequences of SEQ ID NO: 1 or 3).

Drawings

1. The drawings are objected to because Figures 7A, 7C, 8A, and 9A are not labeled. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing

should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities:

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (See for example, page 8, line 10; page 14, line 11; page 16, line 29; page 30, line 31; page 76, lines 13-15, 17, 19). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "HUMAN SLC26A6 ANION EXCHANGER POLYPEPTIDES".

Appropriate correction is required.

Claim Objections

5. Claims 2-3 are objected to because of the following informalities:

6. Claims 2 and 3 recite non-elected inventions (SEQ ID NOs).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 4-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 4-9 recite the limitation "the functional property" in line 2 (see for example, claims 4-8). There is insufficient antecedent basis for this limitation in the claim.

10. Claim 10 recites the limitation "the Cl^--base exchange" in line 2. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 3 is rejected as being indefinite because claim 3(d) is unclear. For example, the meaning of the phrase "...(a), (b), and (c) above in nucleic acid sequence due to the degeneracy of the genetic code, and which encodes a functional SLC26A6 polypeptide encoded by the isolated nucleic acid of one of (a), (b), and (c) above" was unable to be determined by the Examiner.

35 USC § 101 and 35 U.S.C. § 112, first paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 2-10 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Claims read on a product of nature in that the claimed polynucleotide is not "isolated". In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty,* 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated" or "purified" as taught by pages 75-76 of the specification. See MPEP 2105.

13. Claims 1-10 and 17-18 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation.

Claim 1 is directed to an isolated polypeptide comprising a functional SLC26A6 polypeptide having at least about 99% sequence identity to SEQ ID NO: 2. Claim 2 is directed to a functional SLC26A6 polypeptide comprising (a) a polypeptide encoded by a nucleic acid of SEQ ID NO: 1 or 3; (b) a polypeptide encoded by a nucleic acid having at least about 70% identity to SEQ ID NO: 1 or 3; (c) a polypeptide comprising an amino acid sequence of SEQ ID NO: 2 or 4; (d) a polypeptide having at least about 85% sequence identity to SEQ ID NO: 2 or 4.

Claim 3 recites that the functional SLC26A6 polypeptide is encoded by an isolated nucleic acid segment selected from the group consisting of (a) an isolated nucleic acid molecule encoding a polypeptide of SEQ ID NO: 2 or 4; (b) an isolated nucleic acid molecule of SEQ ID NO: 1 or 3; (c) an isolated nucleic acid molecule which hybridizes to a nucleic acid sequence of SEQ ID NO: 1 or 3; (d) an isolated nucleic acid molecule differing by at least one functionally equivalent codon from the isolated nucleic acid molecule of one of (a), (b), and (c) above. Claims 4-10 recite functional properties of the SLC26A6 polypeptide. Claim 17 is directed to an isolated human SLC26A6 polypeptide. Claim 18 recites that the SLC26A6 polypeptide further comprises (a) a polypeptide of SEQ ID NO 2; or (b) a polypeptide encoded by a nucleic acid molecule of SEQ ID NO: 1.

The specification discloses that the "terms "SLC26" and terms including "SLC26" also refer to polypeptides comprising Na+-independent anion transporters that transport SO_4^{2-}, Cl^-, formate, and/or oxalate, and to nucleic acids encoding the same" (page 16, lines 23-25). However, the instant specification does not teach any significance or functional characteristics of the human SLC26A6 polypeptide of SEQ ID NO: 2 or 4. The specification also does not disclose any methods or working examples that indicate the human polypeptides of the instant invention are involved in any activity. There is no biological activity, phenotype, disease or condition, ligand/anion, binding partner, or any other specific feature that is disclosed as being associated with human SLC26A6. Without any information as to the specific properties of human SLC26A6, the mere identification of the polypeptide is not sufficient to impart any particular utility to the claimed polypeptides. Since significant further research would be required of the skilled artisan to determine how the claimed polypeptides are involved in any

activities, the asserted utilities are not substantial. Since the utility is not presented in mature form and significant further research is required, the utility is not substantial. The specification asserts the following as patentable utilities for the claimed putative polypeptides (SEQ ID NOs: 2, 4):

1) to identify a modulator of anion transport (page 6, lines 25-33 through page 7, lines 1-11; page 40, lines 25-32 through page 42; page 47, lines 10-33 though page 56)

2) to produce a variant polypeptide (pages 27-29)

3) to produce antibodies (pages 39-40)

4) to characterize a mutant SLC26 polypeptide linked to a disorder of anion transport (page 42, lines 32-33 through page 43, lines 1-3)

5) to determine altered levels of SLC26 polypeptide expression (page 56, lines 26-32 through page 58, lines 1-4)

Each of these shall be addressed in turn.

1) to identify a modulator of anion transport. This asserted utility is not specific or substantial. Such assays can be performed with any polypeptide. Additionally, the specification discloses nothing specific or substantial for the modulators that can be identified by this method. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

2) to produce a variant polypeptide. This asserted utility is not specific or substantial. Such assays can be performed with any polypeptide. Further, the specification discloses nothing specific or substantial for the variant polypeptide that is produced by this method. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

3) to produce antibodies. This asserted utility is not specific or substantial. Antibodies can be made to any polypeptide. However, if the specification discloses nothing specific and substantial about the polypeptides, therefore both polypeptides and their antibodies have no patentable utility. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

4) to characterize a mutant SLC26 polypeptide linked to a disorder of anion transport. This asserted utility is not specific or substantial. The specification does not disclose any mutant SLC26A6 polypeptides. Significant further experimentation would be required of the skilled artisan to identify such a mutant polypeptide and disorders of anion transport associated with it. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

5) to determine altered levels of SLC26 polypeptide expression. This asserted utility is not specific or substantial. Such assays can be performed with any polypeptide. The specification discloses nothing about the normal levels of expression of the polypeptides. The altered or abnormal levels of the polypeptides cannot be determined until a baseline control level is established. The specification also does not disclose if any diseases disorders are associated with normal or altered levels or forms of the SLC26A6 polypeptides. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

The specification of the instant application discloses that the SLC26 gene family has been highly conserved during evolution, but that individual family members have diverse

physiological roles (page 4, lines 7-30). The state of the art at the time the invention was made discloses that in humans, four SLC26 had been cloned, SLC26A2, SLC26A3, SLC26A4, and SLC26A5 (Lohi et al. Genomics 70: 102-112, 2000; page 102, column 2). Lohi et al. also teach that SLC26A2, SLC26A3, and SLC26A4 genes are the disease genes mutated in diastrophic dysplasia, congenital chloride diarrhea, and Pendred syndrome, respectively (page 102, column 2, first full paragraph). Additionally, Lohi et al. state that the three closely related but highly tissue-specific human anion transporters play central roles in the etiology of phenotypically different recessive diseases (page 102, column 2). Lohi et al. also points that SLC26A3 transports chloride, bicarbonate, hydroxyl, sulfate, and oxalate, whereas SLC26A4 transports iodide, formate, and chloride (but not sulfate) (Lohi et al., bottom of page 102 through the top of page 103, column 1). Thus, Lohi et al. concludes that the SLC26 transporters have distinct profiles for anion specificity (page 102, column 2). Mount et al. (Pflugers Arch Eur J Physiol 447: 710-721, 2004) also teach that that the SLC26 anion exchangers play a role in different physiological processes, such as skeletal development, synthesis of thyroid hormone, transepithelial NaCl transport, bicarbonate excretion by the distal nephron, and bicarbonate secretion by the exocrine pancreas (page 710, column 2, first full paragraph). Mount et al. also echo Lohi et al. by stating that "[i]ndividual paralogs differ significantly in anion specificity" (page 710, column 2, 2nd full paragraph).

Furthermore, regarding the polypeptides claimed in the instant invention, the prior art reference of Waldegger et al. (Genomics 72: 43-50, 2001) discloses a human SLC26A6 polypeptide that is 99.7% to the amino acid sequence of SEQ ID NO: 2 of the instant application (see sequence alignment attached to the instant Office Action as Appendix A). Waldegger et al.

also teach a human SLC26A6 polypeptide that is 100% to the amino acid sequence of SEQ ID NO: 4 of the instant application (see sequence alignment attached to the instant Office Action as Appendix B). Importantly, Waldegger et al. state that "[e]xpression in MDCK cells and in *Xenopus* oocytes demonstrated trafficking of the SLC26A6 protein to the cell membrane but did not reveal anion transport activity with tracer uptake or intracellular pH measurements" (page 43, abstract; page 47, column 2, 2nd full paragraph; page 48, column 1; emphasis added by Examiner). Thus, given the paucity of information in the instant specification and the state of the art at the time the invention was made, significant further research would have been required of the skilled artisan to determine whether the claimed human SLC26A6 polypeptides of SEQ ID NOs: 2 and 4 transport any anions or are associated with a specific disease or disorder. There is little doubt that, after complete characterization, this DNA and protein, may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete.

14. Claims 1-10 and 17-18 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

14a. However, even if the claimed invention is eventually deemed to have a credible, specific and substantial asserted utility or a well established utility, claims 1-10 and 17-18 would remain rejected under 35 U.S.C. § 112, first paragraph. Specifically, the specification teaches that "the

term "SLC26A" and terms including "SLC26" (e.g., SLC26A6, SLC26A1, and SLC26A2) refer generally to isolated SLC26 nucleic acids, isolated polypeptides encoded by SLC26 nucleic acids, and activities thereof. SLC26 nucleic acids and polypeptides can be derived from any organism" (page 16, lines 13-17). The specification discloses that a protein substantially identical to a SLC26 protein comprises an amino acid sequence that is at least about 35% to about 45%, more preferably at least about 45% to about 55% identical, even more preferably at least about 55% to about 65% identical, still more preferably at least about 65% to about 75% identical, still more preferably at least about 75% to about 85% identical, and still more preferably at least about 85% to about 95% identical, and still more preferably at least 95% to about 99% identical to any one of even-numbered SEQ ID NOs: 2-12 when compared over the full length of a SLC26 polypeptide (page 27, lines 1-13). It is noted that the Examiner has broadly interpreted phrases such as "a polypeptide comprising an amino acid sequence…" (claim 2(c) for example), "a polypeptide of SEQ ID NO: 2" (claim 18(a)), and "a polypeptide encoded by a nucleic acid molecule of SEQ ID NO:1" (claim 18(b), for example)) as reading upon polypeptide fragments of SEQ ID NOs: 2 and 4 and nucleic acid fragments encoding such. The Examiner has also broadly interpreted claim 17 ("[a]n isolated human SLC26A6a polypeptide") as reading upon any polypeptide fragment, derivative, mutant, or variant of SEQ ID NO: 2.

However, the specification does not teach any variant, fragment, or derivative of the SLC26A6 polypeptides other than the full-length amino acid sequences of SEQ ID NOs: 2 and 4. The specification also does not teach functional or structural characteristics of the polypeptide variants, fragments, and derivatives derivatives recited in the claims.

The problem of predicting protein and DNA structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and DNA is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions (see Wells, 1990, Biochemistry 29:8509-8517; Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495). However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the DNA and protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. The art recognizes that function cannot be predicted from structure alone (Bork, 2000, Genome Research 10:398-400; Skolnick et al., 2000, Trends in Biotech. 18(1):34-39, especially p. 36 at Box 2; Doerks et al., 1998, Trends in Genetics 14:248-250; Smith et al., 1997, Nature

Biotechnology 15:1222-1223; Brenner, 1999, Trends in Genetics 15:132-133; Bork et al., 1996, Trends in Genetics 12:425-427).

It is noted that the specification of the instant application even discloses that the SLC26 gene family has been highly conserved during evolution, but that individual family members have diverse physiological roles (page 4, lines 7-30). Lohi et al. teach that SLC26A2, SLC26A3, and SLC26A4 genes are the disease genes mutated in diastrophic dysplasia, congenital chloride diarrhea, and Pendred syndrome, respectively (page 102, column 2, first full paragraph). Additionally, Lohi et al. state that the three closely related but highly tissue-specific human anion transporters play central roles in the etiology of phenotypically different recessive diseases (page 102, column 2). Lohi et al. also points that SLC26A3 transports chloride, bicarbonate, hydroxyl, sulfate, and oxalate, whereas SLC26A4 transports iodide, formate, and chloride (but not sulfate) (Lohi et al., bottom of page 102 through the top of page 103, column 1). Thus, Lohi et al. concludes that the SLC26 transporters have distinct profiles for anion specificity (page 102, column 2).

Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

15. Claims 1-10 and 17-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is directed to an isolated polypeptide comprising a functional SLC26A6 polypeptide having at least about 99% sequence identity to SEQ ID NO: 2. Claim 2 is directed to a functional SLC26A6 polypeptide comprising (a) a polypeptide encoded by a nucleic acid of SEQ ID NO: 1 or 3; (b) a polypeptide encoded by a nucleic acid having at least about 70% identity to SEQ ID NO: 1 or 3; (c) a polypeptide comprising an amino acid sequence of SEQ ID NO: 2 or 4; (d) a polypeptide having at least about 85% sequence identity to SEQ ID NO: 2 or 4. Claim 3 recites that the functional SLC26A6 polypeptide is encoded by an isolated nucleic acid segment selected from the group consisting of (a) an isolated nucleic acid molecule encoding a polypeptide of SEQ ID NO: 2 or 4; (b) an isolated nucleic acid molecule of SEQ ID NO: 1 or 3; (c) an isolated nucleic acid molecule which hybridizes to a nucleic acid sequence of SEQ ID NO: 1 or 3; (d) an isolated nucleic acid molecule differing by at least one functionally equivalent codon from the isolated nucleic acid molecule of one of (a), (b), and (c) above. Claims 4-10 recite functional properties of the SLC26A6 polypeptide. Claim 17 is directed to an isolated human SLC26A6 polypeptide. Claim 18 recites that the SLC26A6 polypeptide further comprises (a) a polypeptide of SEQ ID NO 2; or (b) a polypeptide encoded by a nucleic acid molecule of SEQ ID NO: 1.

The instant claims do not require that the polypeptides possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polypeptides that is defined only by sequence identity. The instant specification teaches that "the term "SLC26A" and terms including "SLC26" (e.g., SLC26A6, SLC26A1, and SLC26A2) refer generally to isolated SLC26 nucleic acids, isolated polypeptides encoded by SLC26 nucleic acids, and activities thereof. SLC26 nucleic acids and polypeptides can be derived from any organism" (page 16, lines 13-17). The specification discloses that a protein substantially identical to a SLC26 protein comprises an amino acid sequence that is at least about 35% to about 45%, more preferably at least about 45% to about 55% identical, even more preferably at least about 55% to about 65% identical, still more preferably at least about 65% to about 75% identical, still more preferably at least about 75% to about 85% identical, and still more preferably at least about 85% to about 95% identical, and still more preferably at least 95% to about 99% identical to any one of even-numbered SEQ ID NOs: 2-12 when compared over the full length of a SLC26 polypeptide (page 27, lines 1-13). It is noted that the Examiner has broadly interpreted phrases such as "a polypeptide comprising an amino acid sequence…" (claim 2(c) for example), "a polypeptide of SEQ ID NO: 2" (claim 18(a)), and "a polypeptide encoded by a nucleic acid molecule of SEQ ID NO:1" (claim 18(b), for example)) as reading upon polypeptide fragments of SEQ ID NOs: 2 and 4 and nucleic acid fragments encoding such. The Examiner has also broadly interpreted claim 17 ("[a]n isolated human SLC26A6a polypeptide") as reading upon any polypeptide fragment, derivative, mutant, or variant of SEQ ID NO: 2.

To provide adequate written description and evidence of possession of a claimed genus,

the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Additionally, the description of two polypeptide species (SEQ ID NOs: 2, 4) is not adequate written description of an entire genus of functionally equivalent polypeptides which incorporate all variants and fragments, including variants and fragments with at least 85% and 99% sequence identity to the polypeptide comprising the amino acid sequence of SEQ ID NO: 2 or 4. The description of two nucleic acid species (SEQ ID NOs: 1 and 3) that encode the polypeptides of SEQ ID NOs: 2 and 4, respectively, is not adequate written description of an entire genus of functionally equivalent nucleic acids which incorporate all variants and fragments, including variants and fragments with at least 70% sequence identity to the nucleic acid sequences of SEQ ID NOs: 1 and 3.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

The skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides and nucleic acids, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only (1) an isolated polypeptide consisting of the amino acid sequence of SEQ ID NO: 2 or 4 and (2) an isolated polypeptide encoded by the nucleic acid sequence of SEQ ID NO: 1 or 3, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 1-3 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillman et al. (WO 200026245; 11 May 2000).

Hillman et al. teach an isolated polypeptide that is 99.9% identical to the amino acid sequence of SEQ ID NO: 2 of the instant application (see sequence alignment attached to the instant Office Action as Appendix C; see Hillman et al., page 62, Table 2; SEQ ID NO: 12). Hillman et al. also disclose that the isolated polypeptide is 99.5% identical to the amino acid sequence of SEQ ID NO: 4 of the instant application (see sequence alignment attached to the instant Office Action as Appendix D; see Hillman et al., page 62, Table 2; SEQ ID NO: 12). Hillman et al. teach an isolated nucleic acid molecule that encodes a SLC26A6 polypeptide that is 99.9% identical to SEQ ID NO: 2 of the instant specification (see sequence alignment attached to the instant Office Action as Appendix E (section I); see SEQ ID NO: 29 of Hillman et al.). It is also noted that nucleic acid molecule of SEQ ID NO: 29 of Hillman et al. is 97.0% identical to the nucleic acid molecule of SEQ ID NO: 1 of the instant application (see sequence alignment attached to the instant Office Action as Appendix E (section II).

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB
Art Unit 1647
18 December 2007

/Bridget E Bunner/
Primary Examiner, Art Unit 1647